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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/551,294 | 11/22/2006 | Debbie Stevens-Wright | B1075.71016US01 | 1798 |

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| EXAMINER |
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PEFFLEY, MICHAEL F

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| ART UNIT | PAPER NUMBER |
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3739

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| MAIL DATE | DELIVERY MODE |
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09/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/551,294 | Applicant(s) STEVENS-WRIGHT, DEBBIE | |
| | Examiner Michael Peffley | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 14-16, 20, 23-25, 27, 30 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 6 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-10, 12, 14-16, 20, 23-25, 27, 30 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received July 26, 2010, have been fully considered by the examiner. The following is a complete response to the July 26, 2010 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 2, 9, 10, 12, 14-16, 20, 23-25, 27, 30 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al (6,409,722) in view of the teachings of the articles to Zhang et al ("Noncontact Radio-Frequency Ablation for Obtaining Deeper Lesions") and Jain et al ("A Three-Dimensional Finite Element Model of Radiofrequency Ablation with Blood Flow and its Experimental Validation").

Hoey et al disclose another system that provides various feedback data to control the output of an RF ablation device. Specifically, Hoey et al disclose a flow sensor and an impedance and temperature feedback system to provide feedback to a controller to control the output parameters of the electrosurgical generator. The output power, voltage, current and the flow rate may all be controlled based on sensed conditions (Abstract). Hoey et al fail to teach providing a signal related to the distance of the ablation electrode from tissue as part of the feedback data used to control the energy output, and also fails to disclose the use of blood flow as a feedback signal.

Zhang et al teach that it is generally known to vary fluid flow rates and energy from the generator based on the distance of the electrode from the tissue being treated (see Abstract). The distance was maintained using spacers to provide a desired

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distance from the electrode to the tissue in a non-contact ablation procedure. The user would select the desired spacing when setting the output for the generator for the procedure.

As addressed in the previous Office action, Jain et al teach in the article that it is generally known that blood flow provided around a probe effects the cooling of an RF electrode, and that it is advantageous to provide a feedback signal of the blood flow around a probe in order to more accurately control the temperature of an RF probe in the body.

To have provided the Hoey et al system with a spacing element to provide for non-contact ablation of a target tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Zhang et al. To have further provided the specific spacing used as an input to the controller to control the output parameters of the system would have been an obvious consideration, particularly since Zhang et al teach that it is known to vary output parameters based on the fluid flow rate and distance of the electrode from tissue. Further, the use of blood flow as a feedback parameter to control the output of the RF generator would also be an obvious consideration for the skilled artisan since Jain et al fairly teach it is known to monitor and use such a parameter to control the output of an RF source.

Claims 3, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al (6,409,722) in view of the teaching of the articles to Zhang et al ("Noncontact Radio-Frequency Ablation for Obtaining Deeper Lesions") and Jain et al

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("A Three-Dimensional Finite Element Model of Radiofrequency Ablation with Blood Flow and its Experimental Validation") and further in view of the teaching of Rittman, III et al ('969).

While it would be intuitive to use algorithms and/or finite element modeling to arrive at the specific relationships between the various feedback parameters and the generator output of the Hoey et al system, there is no express disclosure in Hoey of using such an analysis in generating the output relationships between the generator and the feedback signals.

Rittman, as addressed previously, disclose an analogous RF ablation system that includes a controller that receives various input signals and correlates the input signals into desired output parameters for the RF generator. In particular, Rittman teach of using various algorithms, finite modeling and other relationships for correlating the output parameters of the RF generator to the input signals (col. 14, lines 10-22).

To have provided the Hoey et al system, as modified by the teachings of Zhang et al and Jain et al, with an algorithm or modeling program to correlate the generator output to the received feedback signals would have been an obvious modification for one of ordinary skill in the art since Rittman fairly teaches it is generally known to use such algorithms and modeling in an analogous system.

Response to Arguments

Applicant's arguments filed July 26, 2010 have been fully considered but they are not persuasive.

Again, the examiner maintains that applicant's arguments are directed towards the bodily incorporation of the Zhang and Jain references. It is not necessary for every element of these references to be combined. Rather, it is what one of ordinary skill in the art would glean from the teachings that forms the basis of the rejection. While Zhang may suggest that fluid flow may not be critical in specific spacing examples, Zhang does still teach that the distance the electrode is spaced from the tissue is a parameter that may be used to control the output of energy delivery to the electrode. The examiner maintains there is sufficient suggestion to the skilled artisan that this parameter may be incorporated into Hoey system as another parameter for providing feedback control to control the size of an ablation lesion. Hoey clearly teaches the use of numerous different feedback parameters to create a lesion of a desired size. Similarly, the Jain article clearly teaches that blood flow is yet another parameter that may be of interest in providing feedback to control energy output in an ablation system. The examiner maintains that including these parameters as feedback in the Hoey system to more accurately create a desired lesion would be well within the purview of the skilled artisan. The arguments made in the previous Office action are again made and maintained. The newly added language to claim 1 is inconsequential since Hoey clearly teaches providing the feedback in order to create a lesion of a desired size (col. 6, lines 1-3).

Allowable Subject Matter

Claims 5 and 6 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
March 24, 2010